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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,095	06/30/2003	Wies Ter Laak	2001-1196-1	8141

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EXAMINER

LEITH, PATRICIA A

ART UNIT PAPER NUMBER

1654

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,095

Applicant(s)

TER LAAK ET AL.

Examiner

Patricia Leith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 10-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/30/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-25 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-9 and 23-25 in the reply filed on 8/30/04 is acknowledged. The traversal is on the ground(s) that the Examiner has not provided sufficient evidence to restrict between the Groups. For example, Applicant contends that the restriction between groups I+II and III-VIII was made as a 'process of making and product made'. Applicant is correct, this was an inadvertent error. The relationship between these groups should have properly read 'product and process of using'. It is clear from the Examiner's reasoning, that this was the case. Nonetheless, the Examiner will more keenly address this relationship:

Inventions I+II and III-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, as stated in the previous Restriction requirement, it is apparent that the methods can be carried out with different products; i.e., the method for treating menopausal complaints can be carried

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out with the product of claims 18 or claim 8 for example. Further, the product, as evidenced by the claims themselves, can be used to perform different processes, i.e., the method of Groups III and Group VI. Furthermore, it is clear that each method of Groups III-VIII are drawn to treating an ailment with respective compositions. Thus, it is clear from all of these Groups that the methods may be carried out with different products.

Applicant further argues that Groups III-VIII are not unrelated, and that the Examiner failed to show that the disclosed inventions are not capable of use together. This argument is not found convincing because the methods are patentably distinct; i.e., one method is for treating menopausal complaints, while another method is drawn to alleviating depression and carbohydrate craving for example. One method can be performed without performing another method, especially considering each method is drawn to a different patient category.

The requirement is still deemed proper and is therefore made FINAL.

New claims 23-25 were examined with the elected invention of Group I, claims 1-9 and 23-25. Claims 10-22 were withdrawn from the merits as they are directed toward the non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stack (US 5,221,745) in view of Suzuki et al. (US 5,543,415) and further in view of Meier et al. (2000).

Stack (US 5,221,745) disclosed that compositions which had affinities for the dopamine D2 receptor were useful as antipsychotic and antidepressive orders and further disclose novel benzodioxans which were dopamine D2 receptor agonists (col.6, lines 49-56). Stack did not specifically teach wherein cocoa, or a component thereof was included with the benzodioxans in a composition or wherein the dopamine D2 receptor agonist was specifically a labdane diterpene agonist.

Suzuki et al. (5,543,415) disclosed that xanthine analogs were useful in treating depression (Abstract, Table 1 and Claim 1).

Meier et al. (2000) disclosed that rotundifuran, a labdane diterpenoid phytochemical intrinsic to *Vitex agnus-castus* was a dopamine D2 agonist (p.378, col.2-p.379, col.1 and Table 5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine a dopamine D2 receptor agonist with cocoa (which contained xanthines such as theobromine) or xanthine since each is well known in the art for treating depression. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *prima facie* obvious.

Varying individual levels of constituents in a pharmaceutical preparation was considered routine experimental procedure at the time of the instant invention. One of ordinary skill in the art would have been motivated to modify the proportions of active ingredients in the composition in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above-cited references before him.

Further, because cocoa powders and extracts as well as low fat cocoa contain xanthines, the administration of a different form of cocoa would have been merely experimental variation, routine in the art of pharmacology. One of ordinary skill in the art would have been motivated to administer varying forms of the cocoa in order to make the product more marketable to the consumer.

Although Stack did not specifically state that the dopamine D2 receptor agonists were labdane diterpenoids, it was known that some labdane diterpenoids such as rotundifuran antagonized the dopamine D2 receptor. The choice of a labdane diterpenoids would have merely been a functional equivalent to other dopamine D2 receptor agonists absent sufficient evidence to the contrary. It was already known in the art that dopamine D2 receptor agonists treated psychosis such as depression, thus, an agonist in the form of a labdane diterpenoid would have served the same function as the compounds taught in Stack; to block the dopamine D2 receptor. Thus, the compounds would have acted as functional equivalents and therefore one of ordinary skill in the art would have been motivated to choose a labdane diterpenoid to serve as a dopamine D2 receptor agonist since, as disclosed by Meier et al., rotundifuran, a labdane diterpenoid, would have effectively blocked the dopamine D2 receptor, and thereby effecting depression.

Claims 1-8 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (US 5,543,415) in view of Foster et al. (1999).

The Teachings of Suzuki et al. were discussed *supra*. Suzuki et al. did not specifically teach a composition with cocoa or a cocoa extract in combination with *Cimicifuga racemosa* (aka *Actaea racemosa*, most common name = Black cohosh).

Cimicifuga racemosa, or Black cohosh was known in the art for treating premenopausal disorders as well as treating 'depressive moods' as indicated by Foster et al. (1999) (p. 52).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine Black cohosh with cocoa (which contained xanthines such as theobromine) or xanthine since each is well known in the art for treating depression. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *prima facie* obvious.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

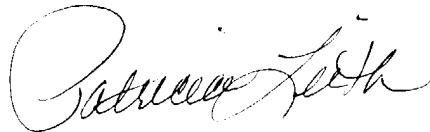
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
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11/04/04

A handwritten signature in cursive script, appearing to read "Patricia Leith", is written over the typed name and title.